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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,480	11/15/2005	Henry Nicolas Jabbour	20747/210	6559

7590 09/18/2007

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EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
09/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,480	JABBOUR ET AL.	
	Examiner	Art Unit	
	Marcos L. Sznaidman	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 22, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *10,11 and 19-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11 pages*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-18) in the reply filed on August 22, 2007 is acknowledged. The traversal is on the ground(s) that there is no burdensome to search and review the method of Group I vs. the pharmaceutical composition of Group II and the intrauterine device of Group III. This is not found persuasive because searching for "a method of treating a pathological condition of the uterus, comprising administering at least one agent that prevents PGF 2 alpha having its effect on the FP receptor" (Group I) requires employing different search queries than searching for "a pharmaceutical composition comprising at least one agent that prevents PGF 2 alpha having its effect on the FP receptor" (Group II) or searching for " a vaginal ring or tampon or an intrauterine device comprising at least one agent that prevents PGF 2 alpha having its effect on the FP receptor" (Group III)

The requirement is still deemed proper and is therefore made FINAL.

Applicant further election of AL-8810 as the specific agent that is an antagonist of the FP receptor is also acknowledged.

Status of claims

Claims 1-31 are currently pending and are the subject of this office action. Claims 1-9 and 12-18 are presently under examination.

Claims 10-11 and 19-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 22, 2007.

Priority

The present application claims priority to foreign application: United Kingdom 0208785.6 filed 04/17/2002.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14-18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-8 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1-8 and 12-13 recite a method for treating or preventing a pathological condition of the uterus in a female individual, the method comprising administering to the individual at least one agent that prevents PGF2 alpha having its effect on the FP receptor. However, the specification discloses only two agents that prevent PGF2 alpha having its effect on the FP receptor: AL-3138 and AL-8810 (see examples 2, 5 and 8), so there is no proof that the applicant was in possession of the broader claim: one agent that prevents PGF2 alpha having its effect on the FP receptor, except for those two specific agents mentioned above (AL-3138 and AL-8810).

For the following discussion claim 1 is given its broadest possible interpretation, where both terms treating and preventing are taking into consideration.

Claim 1-9 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1-9 and 12-13 recite a method for treating or preventing a pathological condition of the uterus in a female individual, the method comprising administering to the individual at least one agent that prevents PGF2 alpha having its effect on the FP receptor. However, the specification fails to disclose any data to support the fact that using this method could prevent the pathological condition of the uterus in a female individual. There is also no evidence in the prior art of any treatment that could prevent a pathological condition of the uterus in a female individual. For this reason, one skilled in the art could not use the inventions of claims 1-9 and 12-13, without undue experimentation.

For the following discussion claims 2-5 are interpreted as a method for treating a pathological condition of the uterus in a female individual.

Claims 2-5, also recite methods for treating a pathological condition of the uterus (endometriosis in claim 4, fibroids in claim 5) in a female individual, the method comprising administering to the individual at least one agent that prevents PGF2 alpha having its effect on the FP receptor. However, the specification fails to disclose any data to support this claim. For example: examples 2 (treatment of uterine cancer with FP receptor antagonist), 5 (treatment of fibroids with FP receptor antagonist) and 8 (treatment of endometriosis with FP receptor antagonist) recite a method of treating patients suffering from: uterine cancer (example 2), fibroids (example 5) and endometriosis (example 8), but fail to give any results that demonstrate that after these treatments the patients recovered and/or benefited from these treatments. There is no evidence in the prior art that agents that prevent PGF2 alpha having its effect on the FP

receptor have any effect on patients with the above-described conditions, so the result of examples 2, 5 and 8 are unpredictable. For this reason, one skilled in the art could not use the invention of claims 2-5, without undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14-18 provide for the use of "an agent that prevents PGF2 alpha having its effect on the FP receptor", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1, 6-9 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 and some of its dependent claims (6-9 and 12-13) recite a method for treating or preventing a pathological condition of the uterus in a female individual, the method comprising administering to the individual at least one agent that prevents PGF2 alpha having its effect on the FP receptor. However, the specification only gives examples for treating uterine cancer, fibroids and

endometriosis, so it is not clear what other pathological conditions of the uterus, other than the three mentioned above does the phrase pathological condition of the uterus actually encompass. This renders claims 1, 6-9 and 12-13 indefinite.

Claims 1-9 and 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The abbreviations PGF2 alpha, FP, PGES, EP2 and EP4 are not preceded by the full meaning on their first use in the claims. This renders claims 1-9 and 12-18 indefinite.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear in claim 13 if terms such as "IFTSYLECL" refer to abbreviated compounds or to amino acid sequences. This renders claim 13 indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

For the following discussion claim 1, 6-9 and 12-13 are interpreted as a method for treating a pathological condition of the uterus in a female individual.

Claims 1, 6-9, and 12-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharif et. al. (U.S. patent # 6,441,033, reference cited by the applicant).

Instant claim 1, 8-9, and 12-13, recite a method of treating a pathological condition of the uterus in a female individual, the method comprising administering to the individual at least one agent that: prevents PGF2 alpha having its effect on the FP receptor (specifically AL-8810).

Claim 6 and 7 recite the same limitations as claim 1, wherein the agent that prevents PGF2 alpha having its effect on the FP receptor: prevents or reduces the binding of PGF2 alpha to the FP receptor (claim 6) or affects the interaction between PGF2 alpha and the FP receptor (claim 7).

For instant claims 1, 6-9 and 12-13, Sharif et. al. teach a method for treating uterine cramps, comprising administering an PGF2 alpha antagonist (specifically AL-8810) (see claims 4 and 7). Uterine cramps are encompassed within pathological condition of the uterus.

For the purpose of the following analysis, the term "use" is being interpreted as "method of using." Instant claim 14-18 recite a method of using at least one agent that prevents PGF2 alpha having its effect on the FP receptor, in the manufacture of a medicament. For instant claims 14-18, Sharif et. al. teach a formulation for FP

antagonists (specifically AL-8810) suitable for several routes of administration and the appropriate dose of administration (see lines 1-13, column 13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6-9 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chemtob et. al. (U.S. Patent # 6,300,312) in view of Sharif et. al. (U.S. patent # 6,441,033, reference cited by the applicant).

Instant claim 1, 8-9, and 12-13, recite a method of treating a pathological condition of the uterus in a female individual, the method comprising administering to the individual at least one agent that: prevents PGF2 alpha having its effect on the FP receptor (specifically AL-8810).

Chemtob et. al. teach a method for treating dysmenorrheal (a pathological condition of the uterus) in a female individual, the method comprising administering a Prostaglandin receptor antagonist. Chemtob et. al. do not teach the use of the specific prostaglandin receptor antagonist AL-8810. However Sharif et. al. teach the use of the specific prostaglandin receptor antagonist AL-8810.

At the time of the invention, it would have been prima facie obvious to a person of ordinary skill in the art to use any prostaglandin receptor antagonist, for example AL-8810 described by Sharif et. al. and use it as suggested by Chemtob et. al. for the treatment of a condition of the uterus., thus resulting in the practice of claims 1, 6-9 and 12-13 with a reasonable expectation of success.

Conclusion

No claims are allowed: claims 1, 6-9, and 12-13 are rejected under 35 U.S.C. 102 (e) and, under 35 U.S.C. 112, first paragraph; claims 2-5 are rejected under

35 U.S.C. 112, first paragraph; and claims 14-18 are rejected under 35 U.S.C. 102(e) and under 35 U.S.C. 112, second paragraph. Claims 1-9 and 12-18 are also rejected under 35 U.S.C. 112, second paragraph.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcos L. Sznaidman whose telephone number is 571 270-3498. The examiner can normally be reached on Monday through Friday 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLS

September 5, 2007

Ardin H. Marschel 9/15/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER